K062034

510(k) Summary for the Dimension Vista™ System Drug 1 Calibrator (DRUG 1 CAL – KC410)

SEP – 6 2006

A. 510(k) Number:

B. Analytes: Digoxin (DIG), Lithium (LI), Phenytoin (PTN), Theophylline (THEO), and **Phenobarbital (PHNO)**[1].

C. Type of Test: Calibrator Material

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension Vista™ System Drug 1 Calibrator
(DRUG 1 CAL – KC410)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – Calibrator
2. Classification: Class II
3. Product Code: JIX – Calibrator, Multi-Analyte Mixture
4. Panel: Clinical Chemistry

G. Intended Use: The DRUG 1 CAL is an *in vitro* diagnostic product for the calibration of Digoxin (DIG), Lithium (LI), **Phenobarbital (PHNO)**[1], Phenytoin (PTN) and Theophylline (THEO) methods on the Dimension Vista™ System.

H. Device Description:

DRUG 1 CAL is a liquid, multi-analyte, human serum based product containing digoxin, lithium, phenobarbital, phenytoin, and theophylline. The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are ready for use (no preparation is required). This same product, the Dimension Vista™ System Drug 1 Calibrator (KC410), was previously cleared (K051087) for the calibration of the Phenobarbital (PHNO) method on the Dimension Vista™ System. The calibrator

[1] The Dimension Vista™ System Drug 1 Calibrator was previously cleared for the calibration of Phenobarbital (PHNO) method in the Dimension Vista™ System under K051087.

formulation has not changed. However, additional analytes are being assigned values and included in the intended use. The volume in the vials has also changed from 2.0 mL to 2.5 mL and the claim for punctured vial shelf life is reduced to one day.

I. Substantial Equivalence Information:

	Device	Predicate
Item	**Dimension Vista™ System Drug 1 Calibrator[1]**	**Dimension® Drug Calibrator (K011035)**
Intended Use	The DRUG 1 CAL is an *in vitro* diagnostic product for the calibration of Digoxin (DIG), Lithium (LI), **Phenobarbital (PHNO)[1]**, Phenytoin (PTN) and Theophylline (THEO) methods on the Dimension Vista™ System.	The Drug Calibrator is an in vitro diagnostic product to be used to calibrate the Digoxin (DGNA), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN), and Theophylline (THEO) methods on the Dimension® clinical chemistry system.
Analytes	Digoxin (DIG), Lithium (LI), Phenytoin (PTN), Theophylline (THEO), and **Phenobarbital (PHNO)[1]**.	Digoxin (DGNA), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN), and Theophylline (THEO).
Form	Liquid.	Liquid.
Traceability	DIG, PHNO, PTN, THEO – USP[2]. LI – NIST SRM[3].	DIG, PHNO, PTN, THEO – USP[2]. LI – NIST SRM[3].
Matrix	Human serum based product.	Human serum based product.
Number of Levels	Two levels.	Five levels.

[1] The Dimension Vista™ System Drug 1 Calibrator was previously cleared for the calibration of Phenobarbital (PHNO) method in the Dimension Vista™ System under K051087.
[2] USP – United States Pharmacopeia.
[3] NIST SRM – National Institute of Standards and Technology Standard Reference Material.

J. Standard/Guidance Document Referenced:

1. Guidance: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
   Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004

2. Standards: CEN 13640 Stability testing of In-Vitro Diagnostic Devices
   ISO 14971:2000 Medical devices -Application of risk management to medical devices

K. Performance Characteristics:

1. Stability: Target shelf life for the Dimension Vista™ Drug 1 Calibrator is 12 months. Calibrator shelf life is determined by comparing results of

the product stored at 4°C with control stored at -20°C. The method is calibrated from this stored material. The 4°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined where the allowable shelf life percent change should be less than or equal to:

Analyte	Allowable Shelf life percent change
Digoxin	≤ 4%.
Phenytoin	≤ 8 %
Theophylline	≤ 8 %
Lithium	≤ 5%
Phenobarbital[1]	≤ 8 %

[1] The Dimension Vista™ System Drug 1 Calibrator was previously cleared for the calibration of Phenobarbital (PHNO) method in the Dimension Vista™ System under K051087.

Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc.
A vial punctured by the instrument and stored on board has a stability claim of one day.
An open vial not on instrument, but recapped and stored in a refrigerator has a stability claim of 31 days.

For testing, vials are opened /punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2 – 8 °C. Opened/punctured vials are tested on days 0, 8 hrs, 2, 8, 32 versus freshly opened vials.

2. Traceability: The assigned values of the Drug 1 Calibrator are standardized to the enclosed table of assigned values:

Analyte	Reference Material
Digoxin	USP[2] 120000
Phenytoin	USP 1535507
Theophylline	USP 1653004
Lithium	NIST SRM[3] 924
Phenobarbital[1]	USP 1524001

[1] The Dimension Vista™ System Drug 1 Calibrator was previously cleared for the calibration of Phenobarbital (PHNO) method in the Dimension Vista™ System under K051087
[2] United States Pharmacopeia.
[3] National Institute of Standards and Technology – Standard Reference Material.

3. Bottle Value Assignment:

A Master Pool is manufactured by weighing in Phenobarbital, Digoxin, Phenytoin, Lithium and Theophylline reference material into drug free normal human serum at five levels and stored frozen at -20° C.

The verification of the Master Pool assigned values are compared against previously approved Master Pool values.
The stock solution is made by adding reference materials gravimetrically to stock solution at target concentrations. The stock solution values are verified versus previously approved Master Pool values.
The commercial lot is made by adding calculated quantities of stock solution to drug free normal human serum in appropriate concentrations for two calibrator levels. The concentration of each level is verified by using an instrument calibrated with Master Pools.
The final bottle values for each level of the commercial lot is assigned and verified using multiple instruments by testing N = 45 replicates per level.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Victor M. Carrio
RA/QS Compliance Manager
Dade Behring, Inc
P.O. Box 6101, Mail Stop 514
Newark, DE, 19714-6101

SEP - 6 2006

Re: k062034
Trade/Device Name: Dimension Vista™ Drug 1 Calibrator (KC410)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: July 18, 2006
Received: July 19, 2006

Dear Mr. Carrio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K062034

Device Name:

Dimension Vista™ Drug 1 Calibrator (KC410)

Indications for Use:

The DRUG 1 CAL is an *in vitro* diagnostic product for the calibration of Digoxin (DIG), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN) and Theophylline (THEO) methods on the Dimension Vista™ System.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K062034